

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 16336-001010PC		Date of mailing (day/month/year) 01.03.2000
International application No. PCT/US99/19434		International filing date (day/month/year) 30/08/1999
International Patent Classification (IPC) or both national classification and IPC G01N33/58		Priority date (day/month/year) 31/08/1998
Applicant UNIVERSITY OF WASHINGTON et al.		

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☒ Certain document cited
 - VII ☒ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **31/12/2000.**

Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer / Examiner Thiel, U <hr/> Formalities officer (incl. extension of time limits) Danti, B Telephone No. +49 89 2399 8161
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Response
DOCKETED *SW*
10-1-00



WRITTEN OPINION

International application No. PCT/US99/19434

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*).

Description, pages:

1-36 as originally filed

Claims, No.:

1-30 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6,8-11,14-23
Inventive step (IS)	Claims	1-30
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Section V

- 1) Reference is made to the following documents:

D1: US-A-5 338 686
D2: WO 98 36095 A
D3: DE 44 33 384 A
D4: US-A-5 910 403

- 2) The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1 and 18, and claims 2 - 6, 8 - 11, 14 - 17 and 19 - 23 as dependent thereon is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

- a) D1 discloses the basic concepts according to present claims 1 and 18 of determining the mass isotope enrichment of a subunit from which a biopolymer is formed, and the rates of synthesis and decay of the biopolymer (see col. 2, lines 5 - 7, lines 20 - 38; col. 3, lines 9 - 12; col. 4, line 47; Table 1; chapters III and IV; claims 1 - 9). The methods include administering the isotopically labelled subunits into human subjects.

Moreover, D1 would appear to relate to the particular technical features of present claims 1 - 5, 8, 15 - 17 and 19 - 23 (see loc. cit.).

- b) D2 pertains to an assay for the measurement of DNA synthesis rates which relies on the use of nonradioactive tracer technology. The assays are done in cell culture. Prior to analysis, the biopolymer is separated and fragmented (see page 1, paragraph 1; page 6, line 27 - page 9; pages 11 - 14; pages 37 - 41; claims).

Thus, D2 is prejudicial to the novelty of claims 1 - 6, 8 - 11 and 14 - 17.

- c) D3 discloses toxicological test to determine particular external effects on protein synthesis in living material, namely cells, comprising incubating the living material with a ^{15}N -labelled nitrogen source under standardised conditions for a fixed time and measuring the relative abundance of ^{15}N by isotope analysis of

the living material or a protein fraction thereof.

Consequently, D3 is prejudicial to the novelty of claims 1 - 6.

- 3) Dependent claims 7, 12, 13 and 24 - 30 do not appear to contain any additional features which, in combination with the feature of the claim(s) to which they refer, involve an inventive step (Art. 33(3) PCT).

The said features would appear to be purely conventional, and the advantages resulting therefrom readily foreseeable.

- 4) It is not at present apparent which part of the application could serve as a basis for a new claim which would satisfy the criteria set forth in Article 33(1) PCT. Should the applicant nevertheless regard some particular matter as suitable an independent claim including such particular matter should be filed taking account of Rule 6.3(b) PCT. The applicant should also indicate in the letter of reply the difference vis-à-vis the state of the art and the significance thereof.
- 5) The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

Section VI

The intermediate document D4 (publication date: 08.06.99; filing date: 15.05.97) would appear to disclose or make obvious the subject-matter of claims 1 - 30.

However, it is assumed that the priority of the present application is validly claimed. The present priority date of 31.08.98 is, namely, before the publication date of D4.

Section VII

- 1) The statement on page 1, first paragraph has no bearing on the invention or its background art and thus contravenes, as being irrelevant, Art. 6 and Rule 9.1(iv) PCT.
- 2) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 - D3 is not mentioned in the description, nor are these documents identified therein.
- 3) The sequence ID Nos have been omitted from page 36.